

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Interstate Movement
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Dr. Frisby Smith	PERMIT NUMBER:	P526P-19-02869
ORGANIZATION:	Bayer, CropScience Division - Biologics	APPLICATION NUMBER:	P526-190522-078
ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	FACILITY NUMBER:	3279
MAILING ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	HAND CARRY:	No
PHONE:	916-661-3322	DATE ISSUED:	06/24/2019
FAX:	916-661-3001	EXPIRES:	06/24/2022
DESTINATION:	Bayer, Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605		
RELEASE:	No		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Helicoverpa zea	Egg, Larvae, Pupae	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	
Plutella xylostella	Egg, Larvae, Pupae	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	
Spodoptera frugiperda	Egg, Larvae, Pupae	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Foreign Locations	

PERMIT GUIDANCE

- 1) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 2) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_an_products.shtml

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THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING
PPQ HEADQUARTER OFFICIAL VIA EPERMITS.


Carlos Blanco

DATE

06/24/2019

WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

- 3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 4) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 5) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS authorizes Dr. Frisby Smith, Bayer, CropScience Division Biologics, 890 Embarcadero Drive, West Sacramento, CA, to move eggs, larvae and pupae of *Bacillus thuringiensis*-resistant *Helicoverpa zea*, *Plutella xylostella*, and *Spodoptera frugiperda* from the continental United States, for laboratory research in the USDA-APHIS approved Facility Number 3972 at the address above. All these conditions must be followed:

1.
 - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - The permit number or a copy of the permit must accompany the shipment.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

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2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@usda.gov within one business day of the event triggering a notification.

3. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of Bt-resistant *Helicoverpa zea*, *Plutella xylostella*, or *Spodoptera frugiperda*. The inner/primary package(s) will contain all the regulated pests and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.

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4. Modifications to the containment facility 3972, or any changes that affect the containment of the Bt-resistant *Helicoverpa zea*, *Plutella xylostella*, or *Spodoptera frugiperda* must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).
5. This authorization is not valid for field research, greenhouse work, or release into the environment.
6. Breeding putatively resistant or Bt-resistant species among themselves, or breeding putatively resistant or Bt-resistant species with Bt-susceptible strains may produce Bt-resistant insects and these (>F1) generations must follow all the above described conditions.

No greenhouse or field release is authorized with these Bt-resistant and putatively Bt-resistant *Helicoverpa zea*, *Plutella xylostella*, or *Spodoptera frugiperda*.

7. *Helicoverpa zea*, *Plutella xylostella*, and *Spodoptera frugiperda* putatively, or resistant to *Bacillus thuringiensis* must be maintained under escape-proof conditions in the APHIS-approved Facility Number 3972 area at the work address indicated on this permit. Regulated insects must be removed from this facility or other designated area only with prior authorization from APHIS. Only the evaluated area is authorized for containment. Other rooms require specific approval. Access to this area must be restricted to authorized personnel only.

The capacity of these insects to escape (dig, claw, push, fly, or chew through wood, plastics, or metals) must be considered in containment design.

Collection methods must be available to catch escaping regulated pests.

All materials removed from caging must be thoroughly examined for putatively or Bt-resistant *Helicoverpa zea*, *Plutella xylostella*, and *Spodoptera frugiperda*, and disposed of following the waste disposal condition.


8. WASTE DISPOSAL:

All the listed regulated pests and all items coming in direct contact or exposed to these Bt-resistant insects must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved, 2) or disposed of as medical /biohazard waste with bonded contracted company or, 3) or incinerated, 4) or frozen at minus 20 Celsius (minus 4 Fahrenheit) for 72 hours (Note: this is colder than a conventional

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refrigerator/freezer), 5) or immersed in Sodium Hypochlorite (6 percent household bleach) for at least 60 minutes, or 6) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste as in 1) to 6), must be double bagged prior to disposal.

9. There is to be no further movement or distribution of *Helicoverpa zea*, *Plutella xylostella*, or *Spodoptera frugiperda* within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such regulated pests.
10. All persons working with the listed regulated pests must be informed of these permit conditions. Anyone working with these materials/organisms must agree to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

END OF PERMIT CONDITIONS

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